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NOTICE OF ALLOWANCE AND FEE(S) DUE

27777 7590 10/17/2008

PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 EXAMINER BORIN, MICHAEL L

PAPER NUMBER

1631 DATE MAILED: 10/17/2008

 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNEY DOCKET NO.
 CONFIRMATION NO.

 09/580.491
 05/30/2000
 Kurt Hertogs
 TIBO-0016(VIP0004US)
 8312

TITLE OF INVENTION: MUTATITONAL PROFILES IN HIV-1 PROTEASE AND REVERSE TRANSCRIPTASE CORRELATED WITH PHENOTYPIC DRUG RESISTANCE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(8) DUE	DATE DUE
nonprovisional	NO	\$1510	\$0	\$0	\$1510	01/20/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION NOT THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

appropriate. All further indicated unless correcte maintenance fee notificat	correspondence includired below or directed oth	or tran ig the ierwise	Patent, advance or in Block 1, by (a	ders and notification of the specifying a new corre	maintenance fees v espondence address	vill be and/o	mailed to the current r (b) indicating a sepa	correspondence address as arate "FEE ADDRESS" for
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				<u> </u>				(Signature)
								(Date)
APPLICATION NO.	FILING DATE			FIRST NAMED INVENTOR	3	ATTC	ORNEY DOCKET NO.	CONFIRMATION NO.
09/580,491 TITLE OF INVENTIO PHENOTYPIC DRUG R		PROF	FILES IN HIV-1	Kurt Hertogs PROTEASE AND I	REVERSE TRANS		0-0016(VIP0004US) FASE CORRELATE	8312 D WITH
APPLN, TYPE	SMALL ENTITY	IS	SUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSU	E FEE	TOTAL FEE(8) DUE	DATE DUE
nonprovisional	NO		\$1510	\$0	\$0		\$1510	01/20/2009
EXAM	EXAMINER		ART UNIT	CLASS-SUBCLASS	7			
BORIN, MI	ICHAEL L		1631	435-005000	_			
"Fee Address" indi PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A	ondence address (or Cha 3/122) attached. ication (or "Fee Address 2 or more recent) attach ND RESIDENCE DATA ess an assignee is ident h in 37 CFR 3.11. Comp	nge of " Indicated. Use	Correspondence ation form e of a Customer SE PRINTED ON T		o 3 registered pater ively, the firm (having as a agent) and the namorneys or agents. If a printed. (pp) patent. If an assignment.	memb es of u no nan	per a 2	ocument has been filed for
Please check the appropri	iate assignee category or	catego	ories (will not be pr	inted on the patent):	Individual 🗆 C	orporat	ion or other private gro	oup entity 🗖 Government
4a. The following fee(s) are submitted: Issue Fee Publication Fee (No small entity discount permitted) Advance Order - # of Copies				o. Payment of Fee(s): (Ple A check is enclosed. Payment by credit ca The Director is hereboverpayment, to Dep	rd. Form PTO-2038	is atta	ached.	
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NOTE: The Issue Fee and interest as shown by the r	d Publication Fee (if requeeords of the United Sta	uired) v tes Pat	will not be accepted ent and Trademark	I from anyone other than Office.	the applicant; a reg	istered	attorney or agent; or th	ne assignee or other party in
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This collection of informan application. Confident submitting the completed this form and/or suggestit Box 1450, Alexandria, V Alexandria, Virginia 223	ation is required by 37 C itality is governed by 35 I application form to the ons for reducing this but irginia 22313-1450. DO 13-1450.	FR 1.3 U.S.C USPT rden, sl O NOT	11. The information 122 and 37 CFR O. Time will vary thould be sent to the SEND FEES OR O.	on is required to obtain or 1.14. This collection is educated depending upon the indice Chief Information Offic COMPLETED FORMS T	retain a benefit by stimated to take 12 vidual case. Any co ser, U.S. Patent and O THIS ADDRES:	he pub minute mmen Trader S. SEN	lic which is to file (and s to complete, including ts on the amount of timerk Office, U.S. Dep D TO: Commissioner	d by the USPTO to process) ag gathering, preparing, and me you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450,

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PHILIP S. JOHNSON			BORIN, M	ICHAEL L
JOHNSON & JOHNSON			ART UNIT	PAPER NUMBER
	& JOHNSON PLAZA CK, NJ 08933-7003	1631 DATE MAILED: 10/17/200	8	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.	Applicant(s)
09/580,491	HERTOGS ET AL.
Examiner	Art Unit
Michael Borin	1621

— The MAILING DATE of this communication appears on the All claims being allowable, PROSECUTION ON THE MERITS IS (OR RENet netwith (or previously mailed), a Notice of Allowance (PTOL-65) or other NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. To the Office or upon petition by the applicant. See 37 CFR 1.313 and MPI.	MAINS) CLOSED in this application. If not included appropriate communication will be mailed in due course. THIS This application is subject to withdrawal from issue at the initiative
 This communication is responsive to <u>07/21/2008</u>. 	
2. ☑ The allowed claim(s) is/are <u>7</u> .	
International Bureau (PCT Rule 17.2(a)). * Certified copies not received: Applicant has THREE MONTHS FROM THE "MAILING DATE" of this conceted below. Failure to timely comply will result in ABANDONMENT of the content of the conten	beived. beived in Application No have been received in this national stage application from the mmunication to file a reply complying with the requirements
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Not INFORMAL PATENT APPLICATION (PTO-152) which gives reason	
5. CORRECTED DRAWINGS (as "replacement sheets") must be subrian (a) including changes required by the Notice of Draftsperson's Pate 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendrian Paper No./Mail Date (see 37 CFR 1.84(c)) sheeth sheet. Replacement sheet(s) should be labeled as such in the header 6. DEPOSIT OF and/or INFORMATION about the deposit of BIC attached Examiner's comment regarding REQUIREMENT FOR THE	ent Drawing Review (PTO-948) attached ment / Comment or in the Office action of ould be written on the drawings in the front (not the back) of according to 37 CFR 1.121(d). DLOGICAL MATERIAL must be submitted. Note the
Attachment(s) 1.	Notice of Informal Patent Application Interview Summary (PTO-413), Paper No./Mail Date Examiner's Amendment/Comment Examiner's Amendment/Comment Examiner's Statement of Reasons for Allowance
Michael Borin, Ph.D. Primary Examiner Art Unit: 1631	

Application/Control Number: 09/580,491

Art Unit: 1631

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/21/2008 has been entered.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Applicant arguments that Condra reference does not teach that mutation 88T of HIV protease measured individually correlates with drug resistance are deemed persuasive. Neither there is teaching in prior art on combination of HIV protease mutations 33F and 90M. Consequently, the prior art does not teach detection of mutation in HIV protease in combination with mutations in HIV reverse transcriptase as claimed (even though Examiner maintains that these mutations are anticipated by prior art).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably Application/Control Number: 09/580,491

Art Unit: 1631

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./ Primary Examiner, Art Unit 1631